(1) Except as required by law or covered by an exception set forth in subpart B or subpart C of this part, is likely to interfere with access, exchange, or use of electronic health information; and

(2) If conducted by a health information technology developer, health information network or health information exchange, such developer, network or exchange knows, or should know, that such practice is likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information; or

(3) If conducted by a health care provider, such provider knows that such practice is unreasonable and is likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information.

(b) Until May 2, 2022, electronic health information for purposes of paragraph (a) of this section is limited to the electronic health information identified by the data elements represented in the USCDI standard adopted in §170.213.

Subpart B—Exceptions That Involve Not Fulfilling Requests to Access, Exchange, or Use Electronic Health Information

§171.200 Availability and effect of exceptions.

A practice shall not be treated as information blocking if the actor satisfies an exception to the information blocking provision as set forth in this subpart B by meeting all applicable requirements and conditions of the exception at all relevant times.

§171.201 Preventing harm exception—when will an actor's practice that is likely to interfere with the access, exchange, or use of electronic health information in order to prevent harm not be considered information blocking?

An actor's practice that is likely to interfere with the access, exchange, or use of electronic health information in order to prevent harm will not be considered information blocking when the practice meets the conditions in paragraphs (a) and (b) of this section, satisfies at least one condition from each of paragraphs (c), (d), and (f) of this section, and also meets the condition in paragraph (e) of this section when applicable.

(a) *Reasonable belief.* The actor engaging in the practice must hold a reasonable belief that the practice will substantially reduce a risk of harm to a patient or another natural person that would otherwise arise from the access, exchange, or use of electronic health information affected by the practice. For purposes of this section, ''patient'' means a natural person who is the subject of the electronic health information affected by the practice.

(b) *Practice breadth.* The practice must be no broader than necessary to substantially reduce the risk of harm that the practice is implemented to reduce.

(c) *Type of risk.* The risk of harm must:

(1) Be determined on an individualized basis in the exercise of professional judgment by a licensed health care professional who has a current or prior clinician-patient relationship with the patient whose electronic health information is affected by the determination; *or*

(2) Arise from data that is known or reasonably suspected to be misidentified or mismatched, corrupt due to technical failure, or erroneous for another reason.

(d) *Type of harm.* The type of harm must be one that could serve as grounds for a covered entity (as defined in §160.103 of this title) to deny access (as the term ''access'' is used in part 164 of this title) to an individual's protected health information under:

(1) Section 164.524(a)(3)(iii) of this title where the practice is likely to, or in fact does, interfere with access, exchange, or use (as these terms are defined in §171.102) of the patient's electronic health information by their legal representative (including but not limited to personal representatives recognized pursuant to 45 CFR 164.502) and the practice is implemented pursuant to an individualized determination of risk of harm consistent with paragraph (c)(1) of this section;

(2) Section 164.524(a)(3)(ii) of this title where the practice is likely to, or

in fact does, interfere with the patient's or their legal representative's access to, use or exchange (as these terms are defined in §171.102) of information that references another natural person and the practice is implemented pursuant to an individualized determination of risk of harm consistent with paragraph (c)(1) of this section;

(3) Section 164.524(a)(3)(i) of this title where the practice is likely to, or in fact does, interfere with the patient's access, exchange, or use (as these terms are defined in §171.102) of their own electronic health information, regardless of whether the risk of harm that the practice is implemented to substantially reduce is consistent with paragraph (c)(1) or (2) of this section; or

(4) Section 164.524(a)(3)(i) of this title where the practice is likely to, or in fact does, interfere with a legally permissible access, exchange, or use (as these terms are defined in §171.102) of electronic health information not described in paragraph (d)(1), (2), or (3) of this section, and regardless of whether the risk of harm the practice is implemented to substantially reduce is consistent with paragraph (c)(1) or (2) of this section.

(e) *Patient right to request review of individualized determination of risk of harm.* Where the risk of harm is consistent with paragraph (c)(1) of this section, the actor must implement the practice in a manner consistent with any rights the individual patient whose electronic health information is affected may have under §164.524(a)(4) of this title, or any Federal, State, or tribal law, to have the determination reviewed and potentially reversed.

(f) *Practice implemented based on an organizational policy or a determination specific to the facts and circumstances.* The practice must be consistent with an organizational policy that meets paragraph (f)(1) of this section or, in the absence of an organizational policy applicable to the practice or to its use in particular circumstances, the practice must be based on a determination that meets paragraph (f)(2) of this section.

(1) An organizational policy must:

(i) Be in writing;

(ii) Be based on relevant clinical, technical, and other appropriate expertise;

(iii) Be implemented in a consistent and non-discriminatory manner; and

(iv) Conform each practice to the conditions in paragraphs (a) and (b) of this section, as well as the conditions in paragraphs (c) through (e) of this section that are applicable to the practice and its use.

(2) A determination must:

(i) Be based on facts and circumstances known or reasonably believed by the actor at the time the determination was made and while the practice remains in use; and

(ii) Be based on expertise relevant to implementing the practice consistent with the conditions in paragraphs (a) and (b) of this section, as well as the conditions in paragraphs (c) through (e) of this section that are applicable to the practice and its use in particular circumstances.

§171.202 Privacy exception—When will an actor's practice of not fulfilling a request to access, exchange, or use electronic health information in order to protect an individual's privacy not be considered information blocking?

An actor's practice of not fulfilling a request to access, exchange, or use electronic health information in order to protect an individual's privacy will not be considered information blocking when the practice meets all of the requirements of at least one of the sub-exceptions in paragraphs (b) through (e) of this section.

(a) *Definitions in this section.* (1) The term *HIPAA Privacy Rule* as used in this section means 45 CFR parts 160 and 164.

(2) The term *individual* as used in this section means one or more of the following—

(i) An individual as defined by 45 CFR 160.103.

(ii) Any other natural person who is the subject of the electronic health information being accessed, exchanged, or used.

(iii) A person who legally acts on behalf of a person described in paragraph (a)(1) or (2) of this section in making decisions related to health care as a